REMARKS

Claims 1, 4 – 6, 8 – 10, 13 and 31 are currently pending. Claims 1, 4 – 6, 8 – 10, 13 and 31 have been rejected. Claim 13 is amended. No new matter is introduced by this amendment.

Reconsideration is respectfully requested in light of the remarks presented below.

Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 4 – 6, 8 – 10, 13 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Taylor et al., United States Patent No. 6,083,257 ("Taylor"), in view of Ecer et al., United States Patent No. 4,486,247 ("Ecer"), or in the alternative Taylor in view of Ecer and Kamath et al., United States Patent No. 6,335,029 ("Kamath").

The Examiner's Contentions – Taylor in view of Ecer

The Examiner states that Taylor teaches a metallic stent having a polymer film, but does not teach the stent body comprising a carbon deposit. Ecer is cited for the inclusion of carbon deposits in a stainless steel alloy. The Examiner contends that one of skill in the art would have been motivated to include the carbon deposits of Ecer in the stent body of Taylor as "[i]t is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results." The combination of Taylor and Ecer yields Applicants' claimed invention, in the Examiner's view.

Applicants traverse.

Applicants' Response - Taylor in view of Ecer

First, the combination of Taylor in view of Ecer does not disclose all of the

claim elements. As noted in a recent Board of Patent Appeals and Interferences ("BPAI") decision, *In re Wada and Murphy*, Appeal 2007-3733, application 10/613,220, "[i]t is well settled that the 'Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art.' *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir., 1994)." The BPAI further noted "[w]hen determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.' *In re Ochiai*, 71 F.3d 1565, 1572 (Fed Cir, 1995) (emphasis added)." *Id*.

Neither reference teaches "a molecular carbon deposit present at a depth of not more than about 2000 Å beneath the stent body surface," an element of Applicants' claim 1. As the Examiner admitted, Taylor does not teach carbon deposits. For the disclosure of carbon deposits, the Examiner has cited Ecer, stating that the feature of implantation of carbon deposits "at a depth of not more than about 2000 Å beneath the stent body surface" would have been obvious to one of ordinary skill in the art as the feature amounts to no more than discovering the optimum or workable ranges through routine skill.

As the Examiner correctly pointed out, Ecer discloses implantation of carbon into a metallic surface. However, Ecer discloses "layers of enriched carbon and oxygen content extended from the steel surface to depths of about 2500 angstroms and about 500 angstroms, respectively," to create a "low friction, high wear surface" (Ecer, col. 1, lines 39 – 40). In other words, Ecer deposits carbon into steel to produce a surface that is abrasion resistant. Applicants' claims are directed to stents. A stent must be able to withstand crimping to a sufficiently small diameter to be maneuvered through a lumen, and then radially expanded to the diameter of the lumen into which it is implanted. As a result, a stent has significantly different properties than the metallic members, such as the machine components, cited in Ecer. Because the teachings of Ecer are focused on implantation of carbon and other ions into steel surfaces for abrasion resistance, the teachings of Ecer provide no guidance for the implantation of carbon in a stent to allow for chemical bonding of a subsequently applied

polymer layer.

Moreover, in contrast to the Examiner's assertion, the determination of the proper depth for carbon implantation in a metallic body of a stent is not routine. If the carbon is implanted too deeply, sufficient carbon will not be close enough to the surface to allow for chemical bonding to the polymer layer. Also, the stent may become brittle, and may be subject to cracking or breaking upon expansion, if the carbon is implanted too deeply. On the other hand, the bond with the polymer layer may be insufficient if the carbon is implanted only at or very near to the surface. As the determination of a proper depth requires more than routine skill, the feature is not rendered obvious by the disclosures of Ecer and Taylor.

More significantly, neither reference discloses "the plasma polymerized film layer is chemically bonded to the carbon deposit." Ecer discloses carbon deposits to improve abrasion resistance of steel. There is no disclosure of any layer, polymeric or otherwise, being applied over the surface of the steel in Ecer. Clearly, then, there is no disclosure of chemical bonding to a subsequently applied layer. Taylor discloses coating of a metallic stent with a polymer coating by immersing the stent into a coating solution and removing the solvent, and, for a cross-linked polymer coating, the additional optional step of subjecting the stent to curing at 70 to 75 ºC. There is no disclosure that the coating chemically bonds to the surface of the stent in Taylor. In summary, there is nothing in Taylor or Ecer that would suggest a polymer layer that is chemically bonded to the metal surface of the stent.

In the present case, the Examiner has glossed over the chemical bonding element by stating that "[i]t appears that the product disclosed by Taylor in view of Ecer would be the same or similar as that claimed; especially since both applicant's product and the prior art product have the same final structure of a metallic stent body having a carbon deposit and a polymer film layer." Regardless of whether or not the polymer layer is plasma-polymerized, the polymer layer is chemically bound to the carbon deposits, a feature that the Examiner has not addressed at all. Such failure to address a claim limitation is improper as "'obviousness requires a suggestion of limitations in a claim,' *CFMT,*

Inc. v. Yieldup Intern Corp., 349 F.3d 1333, 1342 (Fed. Cir., 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA, 1974))." *Id.*

Second, not only does the Examiner fail to address all the claim elements, the Examiner has used an improper combination of references in her rejection. It is well established that "it is improper to combine references where the reference teach away from their combination. *In re Grasselli*, 713 F.2d. 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)" Manual of Patent Examining Procedure, 8th Ed., § 2145. The Examiner states that one of skill in the art would have been motivated to modify the stent of Taylor to include the carbon deposits of Ecer as application of "a known technique to a known device ready for improvement" "yield[s] predictable results." Ecer, however, teaches implantation of carbon for the sole purpose of enhancing wear resistance. As noted above, the Taylor stent is entirely coated with a polymeric layer. Therefore, it is inconsistent to increase the wear or abrasion resistance of the metallic surface as the metal surfaces will not be subject to abrasion due to the polymer coating. The predictable results of the improvement, increased abrasion resistance, has no bearing on the problem to be solved, that is improved adhesion of a polymer layer to a metallic stent surface. Thus, Ecer teaches away from the combination with Taylor.

The combination of Taylor and Ecer is also improper for the additional reason that Ecer is non-analogous art. As noted in MPEP § 2141.01, "to rely on a reference under 35 U.S.C. § 103, it must be analogous prior art." Ecer is directed to "steels having high wear resistance and low friction surfaces" and methods for producing such steels. Ecer provides that exemplary uses for such steels are "machines having components, each having surfaces . . . which are in sliding, lubricated contact with each other under a load . . . " (Ecer, column 3, lines 41 – 44). Such a reference is clearly not in the same art as Applicants' claimed invention, that is, implantable medical devices. Applicants acknowledge that a prior art reference does not need to be in the same field to be considered an appropriate reference under 35 U.S.C. § 103 since the Supreme Court recently noted "[u]nder the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or

application at issue] can provide a reason for combining the elements in the manner claimed." *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 420; 127 S. Ct. 1727, 1742; 167 L. Ed. 2d 705, 723; 82 U.S.P.Q.2D (BNA) 1385, 1397 (2007)." Ecer is not such a reference as it addresses the problem of friction and wear resistance, which is in contrast to the problem that Applicants' invention addresses, the adherence of a polymeric layer to a metal substrate of an implantable medical device. Not only is there nothing in Ecer that suggests a solution to this problem, the reason for carbon implantation in Ecer is inconsistent with application of a subsequent layer. Thus, the combination of Taylor and Ecer is clearly improper.

Third, the Examiner has improperly ignored the feature "plasma polymerized." In reaching her conclusion of obviousness, the Examiner has stated that the feature "plasma-polymerized" has not been given any weight as this feature "refers to the process of depositing the polymer film layer and not to the final product created." On page 4 of the Office Action, the Examiner then contradicts herself by stating, with reference to the Kamath reference, "Kamath teaches applying a polymer film to a stent by plasma polymerization," and that "Kamath teaches that this process [plasma polymerization] allows covalent bonding between layers . . . ." Thus, the Examiner's admission that plasma polymerization allows for covalent bonding is clear evidence that a plasma polymerized layer differs from one applied by other means. As the product may be different, the Examiner's failure to give any weight to the feature is improper.

In summary, for all the reasons above, with respect to the combination of Taylor in view of Ecer, the Examiner has not met her burden in establishing a *prima facie* case of obviousness.

The Examiner's Contentions – Taylor in view of Ecer and Kamath

Alternatively, the Examiner rejects the claims over Taylor in view of Ecer, and further in view of Kamath. Kamath is cited for the covalent bonding of one film to another film as a result of plasma polymerization on a stent. According to

the Examiner, to one of ordinary skill in the art, application of the polymer layer of Taylor to the stent as modified by Ecer via the plasma polymerization method of Kamath would have been "obvious to try." In reaching her conclusion, the Examiner has stated "[i]t is well within the general knowledge of one having ordinary skill in the art to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success." Thus, the result would have been a polymer layer chemically bonded to the stent body, including bonding to the carbon deposits that are present within the steel of the stent body.

Applicants traverse.

Applicants' Response - Taylor in view of Ecer and Kamath

The Examiner has not established a *prima facie* case of obviousness. To begin with, the Examiner's conclusion of obviousness is predicated on the existence of carbon deposits in the body of the device. As admitted by the Examiner, neither Kamath nor Taylor teaches implantation of carbon in a stent body. As noted above, for this element, the Examiner has turned to Ecer. Ecer, however, teaches implantation of carbon for the sole purpose of enhancing wear resistance. Kamath, like Taylor, discloses a stent that is entirely coated with a polymeric layer. As noted above, the combination of Taylor and Ecer is impermissible as Ecer teaches away from the combination. Thus, the combination of Taylor in view of Ecer and further in view of Kamath suffers from the same inconsistency. It is inconsistent to increase the wear or abrasion resistance of the metallic surface as the metal surfaces will not be subject to abrasion due to the polymer coating.

Additionally, the discussion above with respect to the impropriety of combining Taylor with Ecer due to the fact that Ecer is non-analogous art is equally applicable to the rejection over Taylor in view of Ecer, and further in view of Kamath. As discussed above, Ecer is in a non-analogous art, and the problem to which Ecer is directed is irrelevant to Applicants' claimed invention. Kamath is also directed to implantable medical devices, an art differing from Ecer. Moreover, Kamath provides no basis for the combination.

Similar to the combination of Taylor in view of Ecer discussed above, the combination of references fail to teach all the elements. As noted above, the combination of Taylor in view of Ecer does not disclose "a molecular carbon deposit present at a depth of not more than about 2000 Å beneath the stent body surface." As Kamath does not disclose implantation of carbon, or any other ions, into a metallic surface, it is abundantly clear that Kamath does not disclose, nor render obvious, "a molecular carbon deposit present at a depth of not more than about 2000 Å beneath the stent body surface." Ecer is the only reference that teaches implantation of carbon atoms into a metallic surface. As previously noted, Ecer provides no guidance for the determination of a proper depth for implantation of carbon into a stent for the purpose of binding a subsequently applied layer because Ecer is directed to implantation of carbon for abrasion resistance. Thus, the feature is neither disclosed, nor rendered obvious, by the references, either alone or in combination.

Also, as Applicants noted above, the combination of Taylor in view of Ecer fails to either disclose or render obvious the feature "the plasma polymerized film layer is chemically bonded to the carbon deposit." In this case, the Examiner has asserted that Kamath's disclosure of a plasma polymerized polymer layer also renders obvious the bonding of the film to the carbon deposits in the metal surface. However, the specific text of Kamath cited by the Examiner teaches "… the plasma polymerization process allows covalent anchoring of the barrier layer 20 to the polymer matrix in the composite layer 5." Thus, Kamath teaches covalent bonding between polymeric layers, and Kamath's teaching does not come even close to the present invention, i.e., chemical bonding of a polymer layer directly the bare metal surface of stent. There is nothing in Kamath that teaches that plasma polymerization results in covalent bonding to a metallic surface, or to a carbon deposit in a metallic surface.

The Examiner side steps the issue by stating that as Kamath teaches plasma polymerization of a polymer layer, it would have been "obvious to try" to apply the layer of Taylor to the stent body as modified by Ecer by plasma polymerization as taught by Kamath. According to the Examiner, such

modification is within the skill of one of the art, as "[i]t is well within the general knowledge of one having ordinary skill in the art to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success." In her response to arguments, the Examiner's proffered rationale for using plasma polymerization is that "doing so may enhance the bond between the stent body surface and polymer film." The Examiner goes on to conclude that "since plasma-polymerization forms chemical bonds," the result is that "the process itself would form a chemical bond between the polymer film and stent body, including the carbon deposits." In sum, the Examiner has based her conclusion upon the assumption that the art is predictable.

Applicants disagree that the plasma process of Kamath is a "predictable solution." As noted above, Kamath does not teach that plasma polymerization results in polymer-metal bonding, but only teaches that the plasma polymerization of one polymer layer allows for covalent (chemical) bonding to the polymer layer below. The Examiner's extrapolation of polymer – polymer bonding to encompass polymer- metal bonding is unreasonable because polymers and metals are different materials. The result of such extrapolation would not be predicable. In summary, there would have been no "reasonable expectation of success," and the Examiner has not met her *prima facie* burden for a showing of obviousness.

Finally, it appears that the Examiner is relying upon hindsight analysis. None of the three references disclose bonding of a polymer layer to carbon deposits, nor do the individual references alone or in combination, render such an element obvious. The only reference disclosing carbon deposits does not involve implantable medical devices, nor does it involve the application of a subsequent layer onto the surface. One of skill in the art would not have looked to a reference directed to methods of altering the surface of steel machine components that are in contact with each other that is directed to solving the problems of wear resistance and abrasion, and apply those methods to an implantable medical device surface for increasing adhesion of a polymer layer to

the metal device surface. It is only with reference to the teaching of Applicants' specification that is the bonding of a layer to carbon deposits in the metallic body, that the Examiner has reached her conclusion.

In summary, the Examiner has not met her burden in establishing a *prima facie* case of obviousness. It appears that the Examiner is interpreting a finding of obviousness to require no more than citation to references disclosing the individual elements. However, this is not the legal basis for obviousness. According to the Supreme Court,

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR International Co. v. Teleflex Inc. et al., 127 S. Ct. 1727, 1741 (2007). It is recognized that this precedent also holds that there need not be a specific teaching, suggestion or motivation in the art. However, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". Id. (citations omitted)(emphasis added).

The Examiner is requested to reconsider and thereupon withdraw the rejection with respect to claim 1. As claim 1 is not rendered obvious by Taylor in view of Ecer, nor by Taylor in view of Ecer and further in view of Kamath, claims 4 – 6, 10, 13, and 31, which depend from claim 1, are patentable over Taylor, Ecer, and Kamath for at least the same reasons that claim 1 is patentable.

Moreover, claim 5 is independently patentable. The broad disclosure of acrylic monomers in Kamath does not render obvious acrylic acid. Neither Taylor

nor Ecer disclose plasma polymerization, and thus do not render obvious the formation of a plasma polymerized polymeric layer from acrylic acid monomers.

CONCLUSION

Applicants believe, based on the above remarks, that this application is in condition for allowance and respectfully request that it be passed to issue.

If necessary to ensure a timely response, this paper should be considered as a petition for an Extension of Time sufficient to provide a timely response. The undersigned authorizes the Commissioner to charge any fees that may be required to the **Squire, Sanders, and Dempsey Deposit Account No. 07-1850**.

Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

Date: May 13, 2009

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